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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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Klaus Sommermeyer

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EXAMINER

WHITE, EVERETT NMN

ART UNIT

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1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/542,944 | SOMMERMEYER, KLAUS | |
| | Examiner | Art Unit | |
| | EVERETT WHITE | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2009 and 15 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-79 is/are pending in the application.
- 4a) Of the above claim(s) 67-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The instant Office Action is in response to the Petition Decision filed July 20, 2009 and the amendment filed March 9, 2009. The amendment filed March 9, 2009 has been received, entered and carefully considered.

Election/Restriction

2. Applicant's election with traverse of Group I in the reply filed on March 9, 2009 is acknowledged. The traversal is on the ground(s) that there is no prior art reference on record that teaches the special technical feature of Claims 61-79, in view of the corresponding "special technical feature" being a carbonic acid diester of hydroxyethyl starch. This argument is not found persuasive in view of the 103 rejection of the claims disclosed below in regard to the Tessler patent (US Re. 28,809).

The requirement is still deemed proper and is therefore made FINAL.

3. Applicants have confirmed that the claims filed July 24, 2008 (Claims 61-79) is the latest version of claims under examination. Claims 67-79 are withdrawn from consideration as being directed to non-elected inventions. Claims 1-60 have been previously canceled.

Disclosure Objection

4. The disclosure is objected to because of the following informalities: On page 10, line 29, the term "p11" should be changed to - - pH - -. On page 3, 5th and 6th paragraph, and page 4, 1st paragraph, the specification recites "claim numbers" which is improper.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 61-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 61-66, being drawn to an aprotic-solvent-soluble carbonic diester of hydroxyethyl starch (HES), is not supported in the instant specification since there appears to be no mention of a carbonic diester of hydroxyethyl starch which is soluble in aprotic solvents. Page 10, lines 18 and 19 of the instant specification discloses that "the reaction to give the inventive carbonic acid diester preferable takes place in an anhydrous aprotic solvent", but this statement is different from a recitation indicating that the carbonic diester of hydroxyethyl starch is soluble in aprotic solvents. Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed.

Also, there is no teaching in the instant specification that the carbonic diester of hydroxyethyl starch has a mean content of from 1:1 to 10:1 of carbonic diester substituents per HES molecule as disclosed in instant Claim 61. On page 10, 4th paragraph, the instant specification states that "the ratio of carbonic acid diesters to polysaccharide and/or polysaccharide derivative in the reaction is in the range of greater than 3:1 to 30:1, preferable 4:1 to 10:1, which is not as the same as 1:1 to 10:1 as instantly claimed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tessler (US Re. 28,809) in view of Benedict (US Patent No. 2,744,894).

Applicant claims an aprotic-solvent-soluble carbonic diester of hydroxyethyl starch (HES), having a mean molecular weight Mw in the range 2000-300000 Dalton, a degree of substitution MS between 0.1 and 0.8, and a C2/C6 ratio of the substituents on the carbon atoms C2 and C6 of the anhydroglucoses between 2 and 15, and having a mean content of from 1:1 to 10:1 of carbonic diester substituents per HES molecule.

The Tessler patent discloses starch esters having the formula:



wherein St represents a starch component (see column 4, line 25), wherein the formula falls within the definition of carbonic diester of a starch product as recited in instant Claim 61. The dependent claims (Claims 62-66) do not recite any features that indicate a starch ester that is different from the starch ester described in the Tessler patent.

The instantly claimed carbonic diester of hydroxyethyl starch differs from the above described product of the Tessler patent by claiming that the starch component thereof is a hydroxyethyl starch.

The Benedict et al patent suggests improvements in water-solubility from hydroxylalkyl etherification as being applicable to starches, particular hydroxyethyl ether (see column 1, lines 15-30). The Benedict et al patent teaches the hydroxyalkyl

starches as being useful as thickener agents, stabilizers for colloidal mixtures or mixtures for suspending solid particles (see column 7, lines 35-40).

One having ordinary skill in the art would have been motivated to combine the teaching of the Tessler patent with the teaching of the Benedict et al patent since both documents are interest in increase stability of the starch products in aqueous compositions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the starch moiety recited in the formulas of the Tessler patent with a hydroxyethyl starch moiety in view of the recognition in the art, as evidenced by Benedict et al patent, that hydroxyethyl starch provides greater stability for aqueous compositions compared to starch containing aqueous compositions.

9. Claims 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buysch et al (US Patent No. 5,068,321) in view of Benedict (US Patent No. 2,744,894).

Applicant claims an aprotic-solvent-soluble carbonic diester of hydroxyethyl starch (HES), having a mean molecular weight Mw in the range 2000-300000 Dalton, a degree of substitution MS between 0.1 and 0.8, and a C2/C6 ratio of the substituents on the carbon atoms C2 and C6 of the anhydroglucoses between 2 and 15, and having a mean content of from 1:1 to 10:1 of carbonic diester substituents per HES molecule.

The Buysch et al patent discloses carbonic acid esters of polysaccharides with a degree of substitution of 0.5 to 3.0 wherein the starch and dextrans are suitable starting materials. Buysch et al teaches the use of the polysaccharide carbonate for additives in cosmetics, flocculating agents for wastewater treatment, and for fixing enzymes (see column 7, lines 5-10 and 15-20)

The instantly claimed carbonic diester of hydroxyethyl starch differs from the carbonic acid esters of starch of the Buysch et al patent by claiming that the starch component thereof is a hydroxyethyl starch.

The Benedict et al patent suggests improvements in water-solubility from hydroxylalkyl etherification as being applicable to starches, particular hydroxyethyl ether (see column 1, lines 15-30). The Benedict et al patent teaches the hydroxyalkyl

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starches as being useful as thickener agents, stabilizers for colloidal mixtures or mixtures for suspending solid particles (see column 7, lines 35-40).

One having ordinary skill in the art would have been motivated to combine the teaching of the Buysch et al patent with the teaching of the Benedict et al patent since both documents are interested in the solubility properties of starch products in aqueous compositions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the starch moiety recited in the formulas of the Buysch et al patent with a hydroxyethyl starch moiety in view of the recognition in the art, as evidenced by Benedict et al patent, that hydroxyethyl starch provides greater solubility for aqueous compositions compared to starch containing aqueous compositions.

10. Claims 61-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaertner et al (US Patent No. 2,868,781) in view of Benedict (US Patent No. 2,744,894).

Applicant claims an aprotic-solvent-soluble carbonic diester of hydroxyethyl starch (HES), having a mean molecular weight Mw in the range 2000-300000 dalton, a degree of substitution MS between 0.1 and 0.8, and a C2/C6 ratio of the substituents on the carbon atoms C2 and C6 of the anhydroglucoses between 2 and 15, and having a mean content of from 1:1 to 10:1 of carbonic diester substituents per HES molecule.

The Gaertner et al patent discloses biscalbohydrate esters of dicarboxylic acids of the formula:



wherein S and S' in the formula represent a carbohydrate that may selected as starch (see column 2, line 11 and lines 55-58), which embraces the carbonic diester starch product recited in the instant claims. The dependent claims (Claims 62-66) do not recite

any features that indicate a starch ester that is different from the starch ester described in the Gaertner et al patent.

The instantly claimed carbonic diester of hydroxyethyl starch differs from the above described product of the Gaertner et al patent by claiming that the starch component thereof is a hydroxyethyl starch.

The Benedict et al patent suggests improvements in water-solubility from hydroxylalkyl etherification as being applicable to starches, particular hydroxyethyl ether (see column 1, lines 15-30). The Benedict et al patent teaches the hydroxyalkyl starches as being useful as thickener agents, stabilizers for colloidal mixtures or mixtures for suspending solid particles (see column 7, lines 35-40).

One having ordinary skill in the art would have been motivated to combine the teaching of the Gaertner et al patent with the teaching of the Benedict et al patent since both documents are interested in the solubility properties of starch products in aqueous compositions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the starch moiety recited in the formulas of the Gaertner et al patent with a hydroxyethyl starch moiety in view of the recognition in the art, as evidenced by Benedict et al patent, that hydroxyethyl starch provides greater solubility for aqueous compositions compared to starch containing aqueous compositions.

Summary

11. Claims 61-66 are rejected; Claims 67-79 are withdrawn from consideration as being directed to non-elected inventions.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623